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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:	)	
	)	
Polyak et al.	)	Examiner: S. E. Saucier
	)	
Serial No.: 09/976,805	)	Group Art Unit: 1651
	)	
Filed: October 12, 2001	)	Atty. Dkt. 122790-00101.2
	)	
For: MACHINE PERFUSION SOLUTION FOR ORGAN AND BIOLOGICAL TISSUE PRESERVATION	)	

DECLARATION OF MAXIMILIAN POLYAK UNDER 37 C.F.R. § 1.132

Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Maximilian Polyak, one of the named inventors of the above-identified patent application, declare as follows.

1. The experiments and graphs described herein were prepared under my supervision and control in order to demonstrate that the present invention is supported by an unexpected result, not taught, suggested, nor contemplated by the prior art.

2. The experiments were performed as follows:

Sprague-Dawley rat kidneys were recovered in the normal fashion and were exsanguinated and cooled to 4°C. Experimental components were added to the solution to test for improvements in post-transplant function (indicated by serum creatinine levels). Five different solutions were prepared for comparison according to Table 1. According to Table 1, the control BELZ solution contains only Belzer solution; the PEG1000 solution contains Belzer

and 1000 µg/L prostaglandin E1; the NTG10 solution contains Belzer and 10 mg/L nitroglycerin; the NAC solution contains Belzer and 0.2 mg/L N-acetylcystein; and the COMB solution contains Belzer, 1000 µg/L prostaglandin E1, 10 mg/L nitroglycerin, and 0.2 mg/L N-acetylcystein. The kidneys were preserved under machine perfusion for 24 hours with the respective solutions, and transplanted into recipient animals. Post-transplant serum creatinine (S. CREAT) was measured hourly for 6 hours.

TABLE 1

	BELZ	PGE1000	NTG10	NAC	COMB
Belzer	+	+	+	+	+
Prostaglandin E1 (1000 µg/L)	-	+	-	-	+
Nitroglycerin (10 mg/L)	-	-	+	-	+
N-Acetylcystein (0.2 mg/L)	-	-	-	+	+

3. The result of the experiment is depicted in Figure 1. Minimal, but statistically insignificant improvements in post-transplant function were observed with prostaglandin E1, nitroglycerin, or N-acetylcystein individually when compared to the control. From this observation, one of ordinary skill in the art would not have expected significant improvement when prostaglandin E1, nitroglycerin, and N-acetylcystein are used together (the COMB solution). However, dramatic improvement was observed with the cumulative effect on post-transplant function of the COMB solution when compared to the control. Because no one individual component demonstrated a substantial improvement compared to the control, a synergistic improvement when all components were added is not expected.

4. In summary, the experiment presented shows an unexpected result that would not have been obvious to one of ordinary skill in the art by reviewing the prior art.

5. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001, and that such willful false statements may jeopardize the validity of the application of any patent issued thereon.

Date: 5/12/05

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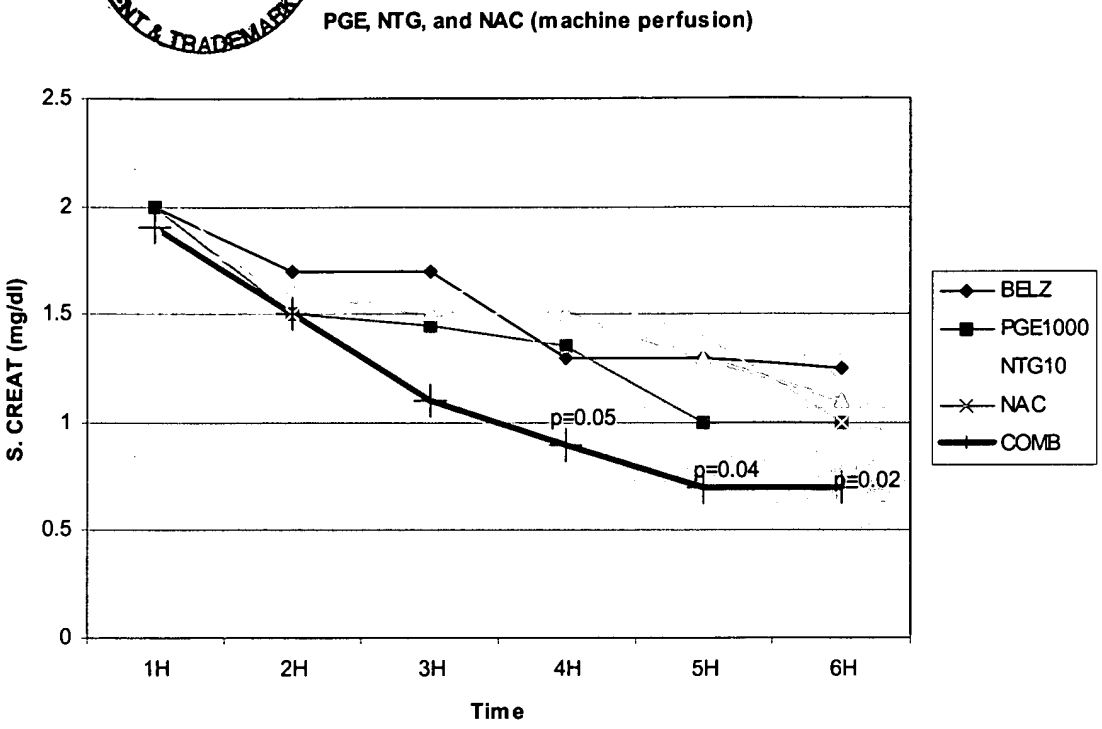


FIGURE 1